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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	09/386,266
Filing Date	August 31, 1999
First Named Inventor	David J. Brayden
Group Art Unit	1645
Examiner Name	S. Devi
Attorney Docket Number	E1067/20020
Customer Number	03000

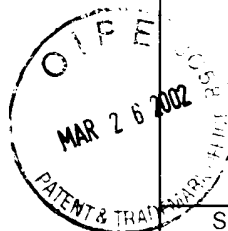
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	AA	5,075,109	424/83	TICE et al.	12/24/1991
	AB	5,362,478	424/9	DESAI et al.	11/08/1994
	AC	5,393,527	435/7.1	MALICK et al.	02/28/1995
	AD	5,417,986	424/49	REID et al.	05/23/1995
	AE	5,439,686	424/451	DESAI et al.	08/08/1995
	AF	5,441,739	434/400	KOSSOVSKY et al.	08/15/1995
	AG	5,529,777	424/184.1	ANDRIANOV et al.	06/25/1996
	AH	5,603,960	424/501	O'HAGAN et al.	02/18/1997
	AI	5,631,263	514/279	PORTOGHESE, et al.	05/20/1997
	AJ	5,674,534	424/501	ZALE, et al.	10/07/1997
	AK	5,709,879	424/450	BARCHFELD, et al.	01/20/1998
	AL	5,807,757	436/535	ANDRIANOV, et al.	09/15/1998
	AM	6,309,669 B1	424/486	SETTERSTROM et al.	10/30/2001

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office	Number	Kind Code (if known)			
	AN		EP 0 154 902		NEURATH, A.R. et al.	02/28/1985	
	AO		WO 86/06635		BIO-TECHNOLOGY AUSTRALIA PTY. LTD., RUSSELL-JONES, G. et al.	11/20/1986	
	AP		EP 0 266 119B1		SOUTHERN RESEARCH INSTITUTE, UNIVERSITY OF ALABAMA AT BIRMINGHAM, TICE, T.R., et al.	10/21/1987	
	AQ		EP 0 333 523		THE UAB RESEARCH FOUNDATION, SOUTHERN RESEARCH INSTITUTE, TICE, T. et al.	03/20/1989	
	AR		EP 0 706 792		THE UAB RESEARCH FOUNDATION, SOUTHERN RESEARCH INSTITUTE, TICE, T., et al.	03/20/1989	
	AS		WO 90/04963		DANBIOSYST UK LIMITED, ILLUM, L. et al.	05/17/1990	
	AT		EP 0 484 621A3		AMERICAN CYANAMID COMPANY, ECKHARDT, T.G. et al.	05/18/1991	
	AU		WO 92/19263		THE U.S.A., REID, R.H. et al.	11/12/1992	
	AV		WO 93/20843		CZINN, S. ET AL.	04/09/1993	

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		Office	Number	Kind Code (If known)			
	AW		WO 93/21950		MEDEVA HOLDINGS BV, ROBERTS, M. et al.	11/11/1993	
	AX		WO 94/06472		INSTITUT PASTEUR, GENGOUX, C. et al.	03/31/1994	
	AY		WO 94/08588		CONSERVATOIRE NATIONAL DES ARTS ET METIERS, MORFIN, R.	04/28/1994	
	AZ		WO 94/09898		GANDER, B., et al.	05/11/1994	
	BA		WO 94/15636		CSL LIMITED, COX, J.	07/21/1994	
	BB		WO 94/21289		THE U.S. OF AMERICA, THE SECRETARY OF THE ARMY, REID, R. et al.	09/29/1994	
	BC		WO 95/02416		VIRUS RESEARCH INSTITUTE, ANDRIANOV, A.K. et al.	01/26/1995	
	BD		WO 95/11008		GENENTECH, INC., CLELAND, et al.	04/27/1995	
	BE		WO 95/11010		GENENTECH, INC., CLELAND, J.L. et al.	04/27/1995	
	BF		EP 0 686 630B1		TAKEDA CHEMICAL INDUSTRIES, LTD., SOHDA, T. et al.	06/05/1995	
	BG		WO 95/13838				
	BH		WO 95/17167		GANDER, B. et al.	06/29/1995	
	BI		WO 95/35097		UNIVERSITY OF NOTTINGHAM, YEH, M. et al.	12/28/1995	
	BJ		EP 0 737 472A1		LG CHEMICAL LIMITED, LEE, H. et al.	03/15/1996	
	BK		WO 96/14876		THE REGENTS OF THE UNIVERSITY OF COLORADO, DUKE, R. et al.	05/23/1996	
	BL		WO 96/20698		THE BOARD OF REGENTS, THE UNIV. MICHIGAN, LEVY, R. et al.	07/11/1996	
	BM		WO 97/17613		ELAN CORPORATION, PLC, O'MAHONY, D.	05/15/1997	
	BN		WO 97/31691		THE UNIVERSITY OF KANSAS, SUBRAMANIAM, et al.	09/04/1997	
	BO		WO 97/32572		THE PENN STATE RESEARCH FOUNDATION, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, EDWARDS, D. et al.	09/12/1997	
	BP		WO 98/51325		CYTOGEN CORPORATION, ELAN CORPORATION, ALVAREZ, V. et al.	11/19/1998	
	BQ		WO 98/51825		ELAN CORPORATION, PLC, CYTOGEN CORPORATION, O'MAHONY, D. et al.	11/19/1998	
	BR		WO 98/58668		MICROBIOLOGICAL RESEARCH AUTHORITY, FARRAR, G.H. et al.	12/30/1998	

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OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate); title of the item (book, magazine, journal, etc.); date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	BS	GREGORIADIS, G., "Preparation of Liposomes", Liposome Technology, Vol. 1, Clinical Research Centre, Middlesex, England, pp.122-129	
	BT	OSTRO, M.J., "Liposomes", From Biophysics to Therapeutics, The Liposome Company, Princeton, New Jersey, pp. 73-108	
	BU	RECHTMAN, D., "Oral Administration of Tetanus Vaccine - Issues Related to Acceptance, Target Populations and Clinical Trials", PharmaMedical Consultants International, pp. 1-11	
	BV	PREIS, I. et al., "A Single-Step Immunization by Sustained Antigen Release", J. Immunol Methods, Vol. 28, No. 1-2, 1979, pp. 193-197	
	BW	UCHIDA et al., "Oral Delivery of Poly(lactide-co-glycolide) Microspheres Containing Ovalbumin as Vaccine Formulation: Particle Size Study" Biol. Pharm. Bull., Vol. 17, No. 9, September 1994, pp. 1272-1276	
	BX	MALOY, K. et al., "Induction of Mucosal and Systemic Immune Responses by Immunization with Ovalbumin Entrapped in Poly(lactide-co-glycolide) Microparticles", Immunology, Vol. 81, 1994, pp. 661-667	
	BY	ULRICH, J. et al., "Monophosphoryl Lipid A as an Adjuvant - Past Experiences and New Directions", Ribi ImmunoChem Research, Inc., Hamilton, Montana 59840, Chapter 21, pp. 495-523, 1995	
	BZ	MOORE, A. et al., "Immunization with a soluble recombinant HIV protein entrapped in biodegradable microparticles induces HIV-specific CD8 ⁺ cytotoxic T lymphocytes and CD4 ⁺ Th1 cells", Vaccine, Vol. 18, October 29, 1995, pp. 1-11	
	CA	MEN, Y. et al., "A single administration of tetanus toxoid in biodegradable microspheres elicits T cell and antibody responses similar or superior to those obtained with aluminum hydroxide", Vaccine, Vol. 13, No. 7, 1995, pp. 683-689	
	CB	DESAI, M.P. et al., "Gastrointestinal uptake of biodegradable microparticles: effect of particle size", Pharmaceutical Research, Vol. 13, No. 12, 1996, pp. 1838-1845	
	CC	MARINARO, M. et al., "Use of Intranasal IL-12 to Target Predominantly Th1 Responses to Nasal and Th2 Responses to Oral Vaccines Given with Cholera Toxin", The Journal of Immunology, 1999, pp. 114-121	
	CD	JONES, D.H. et al., "Orally Administered Microencapsulated Bordetella pertussis Fimbriae Protect Mice from B. pertussis Respiratory Infection", Infection and Immunity, Vol. 64, No. 2, February 1996, pp. 489-494	
	CE	LEE, V., "Pharmaceutical Research", An Official Journal of the American Association of Pharmaceutical Scientists, Vol. 13, No. 9, September 1996, pp. S237-S242	
	CF	RUBAS, W. et al., "An Integrated Method to Determine Epithelial Transport and Bioactivity of Oral Drug Candidates in Vitro", Pharmaceutical Research, Vol. 13, No. 1, 1996, pp. 23-25	
	CG	MCCLEAN, S. et al., "Binding and Uptake of Biodegradable Poly-DL-Lactide Micro- and Nanoparticles in Intestinal Epithelia", European Journal of Pharmaceutical Sciences, 1997, pp. 3-11	
	CH	NUGENT, J. et al., "Design and delivery of non-parenteral vaccines", Journal of Clinical Pharmacy and Therapeutics, Vol. 23, No. 4, August 1998, pp. 257-285	
	CI	BRAYDEN, D.J., et al., "Novel oral drug delivery gateways for biotechnology products: polypeptides and vaccines", Pharmaceutical Science and Technology Today, Vol. 1, No. 7, October 1998 pp. 291-299	
	CJ	SINGH, et al., "The preparation and characterization of polymeric antigen delivery systems for oral administration", Adv. Drug Delivery Rev., December 1998, Vol. 34, No. 2-3, pp. 285-304	
	CK	SINGH, et al., "Controlled release microparticles as a single dose diphtheria toxoid vaccine: immunogenicity in small animal models", Vaccine, February 1998, Vol. 16, No. 4, 1998, pp. 346-352	

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CL

NEWMAN, K. et al., "Delivery of MUC1 Mucin Peptide by Poly(d,l-lactic-co-glycolic acid) Microspheres Induces Type 1 T Helper Immune Responses", Journal of Pharmaceutical Sciences, Vol. 87, No. 11, November 1998, pp. 1421-1428

CM

HAROKOPAKIS, E. et al., "Effectiveness of Liposomes Possessing Surface-Linked Recombinant B Subunit of Cholera Toxin as an Oral Antigen Delivery System", Infection and Immunity, September 1998, Vol. 66, No. 9, pp. 4299-4304

CN

CROYLE, M. et al., "In-Vitro and in-Vivo Assessment of Adenovirus 41 as a vector for gene delivery to the intestine", Gene Therapy, Vol. 5, , 1998, pp.645-654

CO

ROOK, G. et al., "Give Us This Day our Daily Germs", Immunology Today, Vol. 19, No. 3, March 1998, pp. 113-120

CP

RYAN, M. et al., "Distinct T-cell subtypes induced with whole cell and acellular pertussis vaccines in children", Immunology, Vol. 93, 1998, pp. 1-10

CQ

NEWMAN, K. et al., "Ovalbumin Peptide Encapsulated in Poly(d,l lactic-co-glycolic acid) Microspheres is Capable of Inducing a T Helper Type 1 Immune Response", Journal of Controlled Release, Vol. 54, No. 1, 1998, pp. 49-59

CR

CLELAND, J. "Single-administration vaccines: controlled-release technology to mimic repeated immunizations", Tibtech, January 1999, Vol. 17, pp. 25-29

CS

BOYAKA, P. et al., "IL-12 Is an Effective Adjuvant for Induction of Mucosal Immunity", The Journal of Immunology, 1999, pp. 122-128

CT

TOBIO, M. et al., "A Novel System Based on a Poloxamer/PLGA Blend as a Tetanus Toxoid Delivery Vehicle", Pharmaceutical Research, Vol. 16, Nov. 5, 1999, pp. 682-688

CU

SHROFF, K. et al., "Potential for Plasmid DNAs as Vaccines for the New Millennium", PSTT, Vol. 2, No. 5, May 1999, pp. 205-212

CV

Search Report for Application PCT/IE 99/00087

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DATE CONSIDERED

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.